

Pediatric Protocol Review Guide

These are important points to consider as you are reviewing pediatric protocols.

(This is not mandatory; therefore, this form does not require completion or entering into DFS.)

PARAMETER	YES	NO	COMMENT
SCIENTIFIC/PUBLIC HEALTH			
Sufficient Chemistry, Manufacturing, and Controls for human adult and comparative pediatric use			
Sufficient pre-clinical animal data for use in the adult and the proposed pediatric target population			
Previous Experience in Adult Population			
Information on children with condition of interest: e.g., historical review, epidemiology, incidence, prevalence, sex ratio, age at onset, geographic and racial distribution as applicable.			
Number of children with condition proposed to be studied; also consider number of patients with subtypes of the broad condition, as applicable.			
Other available treatments (me too or 1 st in class); approved and or off-label use medication/s.			
Formulation:			
— Dose: e.g. consider proposed dosing by weight (mg/kg or body surface area) rather than by age alone; consider loading dose issues, if applicable.			
— Formulation: e.g., oral suspension, solution, tablet, capsule, sprinkle, etc.			
— Administration: e.g., oral, nasal spray, topical patch, etc.			
ENDPOINT ASSESSMENTS			
Review Proposed Pediatric Study Request Protocol, any Amendments, and the rationale for these proposed amendments			
Review Written Request and any other WR amendments (For products that have WR's)			
Proper Supervision of Trial (e.g. Pediatric Expertise): consider if a Data Monitoring Board (DMB) is advised based on adult safety data; consider use of a pediatric consultant, if designated by the sponsor; consider appropriate IRB/Ethics Committee oversight.			
Safety Monitoring Laboratory Tests			
Blood draw			
— Volume: consider potential need to request proposed blood volume by weight group or age group.			
— Frequency: consider how the proposed scheduled lab monitoring is aligned with the PK/PD parameters of the drug in adult/ pediatric patients.			
Safety			
Serious and Unexpected Events			
Other Significant Information (Known safety concern that has not been systematically studied in pediatrics) frequency, severity, literature; other studies, adult data			
— Potential future safety risks; consider issues to be further evaluated in Phase 4 post-marketing investigations)			
○ All deaths			

PARAMETER	YES	NO	COMMENT
ETHICAL ISSUES			
– Review informed consent: consider a reading level at 6 th to 8 grade.			
– Procedures for obtaining consent*			
– Age-Appropriate Assent Process*			
– Informed Parental Permission*			
❖ One or both parent*			
– Payment compensation for participation*			
o To parent or subject			
o Amount			
o Payment schedule			
– Payment compensation for research related injury*			
– Investigational Review Board Composition (e.g. Pediatric Expertise)*			
– Data Monitoring Committee composition (e.g., Pediatric Expertise)			
– Subpart D regulations: Reviewers may want to keep these criteria in mind (see Subpart D link below)			

*This information may not be included in the current submission. These are issues to keep in mind as you consider whether a prospective inspection is needed for the clinical investigator or IRB.

Helpful Links:

[E11 Clinical Investigation of Medicinal Products in the Pediatric Population](#)

[Subpart D--Additional Protections for Children Involved in Clinical Trials](#)

Pediatric Advisory Subcommittee Meetings--Consensus Statements

- o [April 24, 2001](#)
- o [September 11, 2000](#)
- o [November 15, 1999](#)

[The Best Pharmaceuticals for Children Act](#)

[The Pediatric Research Equity Act](#)

[Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in ...](#)

[Please email comments regarding the Pediatric Protocol Review Tool](#)